



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Adeno-associated virus polynucleotides, polypeptides and virions

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive, Sublicensable Patent License to consolidate co-owned rights to the inventions and the Patents and Patent Applications listed in the Supplementary Information section of this notice to The Children's Medical Research Institute, having a place of business in Westmead NSW, Australia.

DATES: Only written comments and/or applications for a license that are received by the National Heart, Lung, and Blood Institute Office of Technology and Development on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent application(s), inquiries, and comments relating to the contemplated license should be directed to: John R. DeVany, Technology

Transfer Analyst, NHLBI Office of Technology Transfer and Development, Telephone: 301-594-2436; email: john.devany@nih.gov.

SUPPLEMENTARY INFORMATION:

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement:

1. U.S. Provisional Patent Application No. 62/331,188, filed May 3, 2016, entitled “Adeno-Associated Virus Polynucleotides and Virions” [HHSRef. No. E-156-2016-0-US-01]
2. Patent Cooperation Treaty Patent Application No. PCT/US2017/030808, filed May 3, 2017, entitled “Adeno-Associated Virus Polynucleotides and Virions” [HHSRef. No. E-156-2016-0-PCT-02]
3. Australian National Phase Patent Application No. 2017261249, filed October 30, 2018, entitled “Adeno-Associated Virus Polynucleotides and Virions” [HHS Ref. No. E-156-2016-0-AU-03].
4. U.S. Patent No. 10,882,886 issued January 5, 2021, entitled “Adeno-Associated Virus Polynucleotides and Virions” [HHS Ref. No. E-156-2016-0-US-04].
5. European National Phase Patent Application No. 17793239.9 filed December 3, 2018, entitled “Adeno-Associated Virus Polynucleotides and Virions” [HHS Ref. No. E-156-2016-0-EP-05].

The patent rights in these inventions have been assigned to the Government of the United States of America, Sydney Children’s Hospital Network, and the Children’s Medical Research Institute (CMRI), a co-owner of said rights, for commercial development and marketing. The prospective patent license will be for the purpose of consolidating the patent rights to CMRI. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212. The prospective patent license will be worldwide, exclusive, may be limited to those fields of use commensurate in scope with the patent rights, and will be sublicensable.

The subject technology pertains to a “fossilized” AAV-derived endogenous viral element (referred to as mAAV-EVE) within the germline of an ancient lineage of Australian marsupials. This novel AAV coat protein sequence of mAAV-EVE may provide the basis for recombinant AAV vectors with unique biological properties.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless, within fifteen (15) days from the date of this published notice, the National Heart, Lung, and Blood Institute Office of Technology Transfer and Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to this to the grant of the contemplated exclusive patent license.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: June 22, 2021.

Bruce D. Goldstein,
Director,

Office of Technology Transfer and Development,

National Heart, Lung, and Blood Institute.

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